Pharmacist, Ms B

Pharmacist, Ms C

Pharmacy

A Report by the

Health and Disability Commissioner

(Case 15HDC01810)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. Ms A, aged 32 years, was prescribed 30 "TRAMADOL 50mg tabs" for pain relief following a wisdom tooth extraction. On 15 November 2015, Ms A's mother, Mrs E, presented the prescription to a pharmacy for dispensing.

2. Registered pharmacist Ms B interpreted the prescription as being for Arrow-Tramadol 50mg capsules, but mistakenly selected from the shelf 30 fluoxetine 20mg capsules, rather than 30 tramadol 50mg capsules. She repackaged them out of the manufacturer's packaging into a plain white packet, which was then labelled as containing tramadol capsules. Ms B told HDC that she became distracted while labelling the packet and so did not check the contents, as she would usually do and as is required by the pharmacy's Standard Operating Procedures (SOPs).

3. The dispensing was checked by registered pharmacist Ms C, who did not identify the dispensing error. The pharmacy told HDC that it is Ms C's normal practice to open packets to make sure the correct medicine and strength has been selected, as is required by the pharmacy's SOPs, but she thinks that on this occasion she may have opened the packet, seen that the strips of capsules were the same size as that of tramadol capsules, and not removed the strips from the packet for a more thorough check.

4. The dispensing error was discovered by Mrs E a week later. Ms A took up to 20 fluoxetine capsules over the space of one week, and took six capsules (totalling 120mg) on at least one day during this time.

Findings

5. Ms B failed to ensure that she dispensed the correct medication to Ms A on 15 November 2015, in accordance with the professional standards set by the Pharmacy Council of New Zealand and with the pharmacy's SOPs. Ms B failed to provide Ms A with services in accordance with professional and other relevant standards, in breach of Right 4(2) of the Code of Health and Disability Services Consumers' Rights (the Code).[1]

6. Ms C failed to check the medication dispensed to Ms A on 15 November 2015 adequately, in accordance with the professional standards set by the Pharmacy Council of New Zealand and with the pharmacy's SOPs. Ms C failed to provide Ms A with services in accordance with professional and other relevant standards, in breach of Right 4(2) of the Code.

7. The dispensing error was Ms B's and Ms C's alone. The pharmacy had appropriate SOPs in place, as well as a sufficient number of trained staff working at the time. The pharmacy did not breach the Code, and is not vicariously liable for Ms B's or Ms C's breach of the Code.

[1] Right 4(2) states: "Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards."

Complaint and investigation

8. The Commissioner received a complaint from Ms A about the care provided to her by Ms B, Ms C and the pharmacy. The following issues were identified for investigation:

   - *Whether pharmacist Ms B provided Ms A with care of an appropriate standard in November 2015.*
   - *Whether pharmacist Ms C provided Ms A with care of an appropriate standard in November 2015.*
   - *Whether the pharmacy provided Ms A with care of an appropriate standard in November 2015.*

9. An investigation was commenced on 16 February 2016.

10. The parties directly involved in the investigation were:

Ms A	Consumer/complainant
Ms B[2]	Pharmacist/provider
Ms C[3]	Pharmacist/provider
The pharmacy	Provider

Also mentioned in this report:

Mrs E	Ms A's mother

Information gathered during investigation

Background

11. On 15 November 2015, Ms A, aged 32 years, presented to an emergency dentist at a public hospital. Ms A had had a wisdom tooth extraction earlier in the week and was still experiencing pain. She was prescribed 30 "TRAMADOL[4] 50mg tabs" with instructions to take one to two "tabs" three times daily for pain relief.

Dispensing of prescription

12. On 15 November 2015, Ms A's mother, Mrs E, attended the pharmacy to have Ms A's tramadol prescription filled. She waited in the pharmacy while this occurred.

[2] Ms B has been a registered pharmacist since late 2011 and is a member of the Pharmaceutical Society and the New Zealand College of Pharmacists.
[3] Ms C has been registered as a pharmacist in New Zealand since late 2014 and is a member of the Pharmaceutical Society and the New Zealand College of Pharmacists.
[4] Tramadol is a centrally acting synthetic analgesia with opioid effects, and is used to treat moderate to severe pain.

13. Ms B had recently returned from an afternoon tea break, the pharmacy technician working that day had just gone on her break, and it was near home time for Ms C. There were no other prescriptions in progress at the time.

14. Ms B dispensed the medication while Ms C typed a label for the medication. Tramadol comes in two forms in New Zealand, Arrow-Tramadol 50mg capsules and Tramal SR (Sustained Release) 50mg tablets. Ms B interpreted the prescription as being for Arrow-Tramadol 50mg capsules, but mistakenly selected from the shelf 30 fluoxetine[5] 20mg capsules, rather than 30 tramadol 50mg capsules. She repackaged them out of the manufacturer's packaging into a plain white packet, which was then labelled as containing tramadol capsules. Ms B told HDC:

> "While I was in the process of reading the label and when I would usually undertake checking the contents I became distracted when [Ms C] was asking me a question about how she had written the label. This meant I unfortunately missed the step of checking the contents of the box I was labelling. Once it was completed I moved it to the checking bench for [Ms C] to undertake the final check."

Medicine comparisons

15. Arrow-Tramadol 50mg capsules are coloured green/yellow and come in boxes containing 10, 20 or 100 capsules, with blister packs of 10 capsules. The blister packs are opaque.

16. Arrow-Fluoxetine 20mg capsules are green/off-white capsules that come in boxes containing 30 or 90 capsules, with blister packs of 10 capsules. The capsule is visible on one side in the blister pack.

17. Both tramadol capsules and fluoxetine capsules are distributed by the same company and are packaged in boxes with the name of the distributer, the name of the drug and the dosage.

Checking of prescription

18. While Ms C checked the prescription, Ms B went out into the retail area of the pharmacy to put through the prescription fee for Mrs E. Ms C did not discover the dispensing error made by Ms B. The pharmacy told HDC:

> "[Ms C] has said that it is normal practice for her to open packets to make sure the correct medicine and strength has been selected, but thinks that maybe on this occasion she opened the packet, saw that the strips of capsules were the same size as that of tramadol capsules, but didn't remove the strips from the packet for a more thorough check."

Discovery of dispensing error

19. Ms A told HDC that, after commencing the medication dispensed, she experienced blurry vision, insomnia at night, drowsiness in the day, dizziness/light-headedness, increased thrush, a swollen tongue and a dry mouth, and was not able to look after her

[5] Fluoxetine is an antidepressant, with known side-effects including fatigue, diarrhoea, nausea, anxiety, dizziness, headache, insomnia, nervousness, somnolence, and tremor.

children properly. In addition, her dental pain was not relieved, resulting in her having to return to the dentist twice.

20. On 22 November 2015, Mrs E noticed that the medication Ms A had been taking for the previous week was fluoxetine, not tramadol, although the label on the packet stated tramadol. The following day, Ms A visited the pharmacy and informed them of the dispensing error. Ms A had arranged an appointment with her general practitioner (GP) for a check-up, in light of taking the wrong medication. The dispensary manager advised HDC that Ms A reported that she had experienced dizziness and a lack of pain relief. The managing director at the pharmacy called the GP practice prior to the appointment and spoke to a practice nurse, who was not concerned that there would be any adverse effects on Ms A's health.

Incident form completed

21. On 24 November 2015, Ms B completed an incident form which recorded, amongst other details, that Ms A had taken up to 20 capsules over the space of one week and had taken six capsules (totalling 120mg) on at least one day during this time.[6]

The pharmacy's Standard Operating Procedures

22. The pharmacy's Standard Operating Procedure (SOP) *Dispensing 3 — Labelling and Dispensing Medicines (2013)* requires dispensers to: "Check the name, brand, strength and formulation [of the medication dispensed] against the prescription, not the label." This SOP was reviewed on 1 March 2014.

23. The pharmacy's SOP *Dispensing 4 — Accuracy Check (2013)* requires those checking dispensed items to:

> "Check the label and dispensed medicine against the original prescription and the stock supply used to dispense the medicine. This includes:
>
> …
>
> — Formulation, strength and quantity of medicine
> — Open each dispensed bottle or skillet to compare contents with stock supply."

This SOP was also reviewed on 1 March 2014.

Further information — the pharmacy

24. Ms B and Ms C, on their and the pharmacy's behalf, provided Ms A with a formal written apology on 26 November 2015. The letter stated:

> "We apologise without reservation for the dispensing error where the incorrect medication was selected for your dental prescription. We take full responsibility for this error. Fluoxetine was selected by mistake from the shelves and dispensed

[6] Medsafe states that the recommended initial dose for depression is 20mg per day, the recommended dose for bulimia nervosa is 60mg per day, the recommended dose for obsessive-compulsive disorder is 20–60mg per day, and the recommended dose for premenstrual dysphoric disorder is 20mg per day, and that the recommended dose may be increased or decreased, with doses above 80mg per day not having been evaluated systemically.

> by [Ms B] instead of tramadol for pain. This error was not detected when [Ms C] was checking the prescription. As a result you received and took the incorrect medication obtaining no relief for your dental pain, but you were also subject to side-effects from the fluoxetine."

25. The pharmacy told HDC that an incident form was completed and, having investigated the dispensing error, it identified several contributing factors: the medications were in similar boxes and on the same shelf, the medications were in similar foils and have a similar appearance, Mrs E was waiting in the shop, and the prescription was filled during afternoon break times and near home time for Ms C. The pharmacy told HDC:

> "As part of our investigation as to how this happened it became apparent that the [company's] products all have the same appearance in that they have white boxes with the name of the drugs in a similar size font, but different colours. As we store our top twenty products together on one shelf these two products did not have the separation you would expect in a strictly alphabetically organised pharmacy. Following this error, the dispensary team have discussed the arrangement of stock, and how it may or may not have contributed to the error. We have decided that rearrangement of stock is not necessary for helping to prevent a reoccurrence of this error."

However, it has informed a [company] representative of its concerns about the packaging of different medications looking so similar.

26. The pharmacy said that its SOPs were robust, but that steps were missed in the process when Ms A's prescription was dispensed. It held a staff meeting on 24 November 2015 and reiterated to all dispensary staff the importance of double-checking their own work before the final check, and of always opening the container during the final check, to check that what is inside is what has been prescribed. The pharmacy also reminded staff that special care should be taken when dispensing medications that have similar packaging to other medications.

27. After being informed of the dispensing error, the pharmacy paid for Ms A's GP appointment and refunded her prescription fees. It also offered to compensate her for the additional dental costs she incurred through having to return to the dentist twice because her pain was unrelieved, but these were covered by her insurance.

Further information — Ms B

28. Ms B told HDC:

> "Since the complaint I have been more vigilant when dispensing and trying to more consistently double-check my own work before handing it over to the checking pharmacist. This was part of my normal practice but was unfortunately missed on this occasion."

29. Ms B also stated that she is considered a very accurate pharmacist and has a very good checking history.

Further information — Ms C

30. Ms C told HDC:

> "I now realise how important it is to double-check on each step along the process of dispensing starting from receiving a script to handing out a medication. We are responsible for making sure our patients get the right medicine, the right quantity with a correct label and ensure they have a good understanding about their medications. I have also learnt that everyone makes mistakes; I have to check up on the work of my colleagues even when I trust them. Overall I have learnt a lot and realised how careful we have to be when doing our job."

31. Ms C also stated that she regrets this incident and has learnt from it. She told HDC that this error is unprecedented in her career history and that she is committed to making it the last one.

Responses to provisional opinion

32. Responses to the provisional opinion were received from Ms A, Ms B, Ms C and the pharmacy. Ms B and the pharmacy had no further comments. Ms C's feedback has been incorporated into the "information gathered" section of the report where appropriate.

33. Ms A stated:

> "The main reason I complained about what happened is so that it would not happen again to someone else and be a fatal outcome. There needs to be more procedures and double-checking within staff so they don't get complacent with their job."

Relevant standards

34. The Pharmacy Council of New Zealand's *Code of Ethics (2011)* requires that a pharmacist:

> "1.2 Take appropriate steps to prevent harm to the patient and the public.
>
> …
>
> 5.1 Be accountable for practising safely and maintain and demonstrate professional competence relative to your sphere of activity and scope of practice."

35. The Pharmacy Council of New Zealand *Competence Standards for the Pharmacy Profession (2015)* provides that the pharmacist:

> "Domain O3: Supply and administration of medicines
>
> …

O3.2.1 Maintains a logical, safe and disciplined dispensing procedure

O3.2.2 Monitors the dispensing process for potential errors and acts promptly to mitigate them."

Opinion: Ms B — Breach

36. As a registered pharmacist, Ms B was responsible for complying with professional standards. The Pharmacy Council of New Zealand's *Code of Ethics (2011)* provides that a pharmacist must "take appropriate steps to prevent harm to the patient and the public" and "be accountable for practising safely and maintain and demonstrate professional competence relative to [the pharmacist's] sphere of activity and scope of practice". Further, the Pharmacy Council of New Zealand *Competence Standards for the Pharmacy Profession (2015)* requires that a registered pharmacist "maintains a logical, safe and disciplined dispensing procedure" and "monitors the dispensing process for potential errors and acts promptly to mitigate them".

37. The pharmacy's SOP *Dispensing 3 — Labelling and Dispensing Medicines (2013)* requires dispensers to check the name, brand, strength and formulation of the medication dispensed against the prescription.

38. Ms A was prescribed 30 "TRAMADOL 50mg tabs", which Ms B interpreted as 30 Arrow-Tramadol 50mg capsules, as opposed to 30 Tramal SR 50mg tablets. My clinical advisor, general practitioner Dr David Maplesden, advised me:

> "If the prescriber intended to supply the SR preparation the script should have been identified as such. Because the script was potentially confusing, best practice would have been for the pharmacist to check with the prescriber whether [she] intended 50mg capsule or 50mg SR tablet, but there was no risk of harm with the prescribing/dispensing as carried out."

I accept this advice.

39. There is no dispute that Ms B then made two errors on 15 November 2015. She mistakenly selected fluoxetine instead of tramadol, when dispensing Ms A's prescription. The medications were in similar boxes and on the same shelf, as well as being in similar foils and having a similar appearance. In addition, Ms B became distracted and did not check the contents of the packet herself, before handing it over to Ms C to complete the final check. Ms B stated that her normal practice was to double-check her own work before giving it to the checking pharmacist, but on this occasion she did not do so. This is concerning.

40. Ms B failed to ensure that she dispensed the correct medication to Ms A on 15 November 2015, in accordance with the professional standards set by the Pharmacy Council of New Zealand and with the pharmacy's SOPs. I consider that Ms B failed

to provide Ms A with services in accordance with professional and other relevant standards, in breach of Right 4(2) of the Code.

Opinion: Ms C — Breach

41. As a registered pharmacist, Ms C was responsible for complying with professional standards. The Pharmacy Council of New Zealand's *Code of Ethics (2011)* provides that a pharmacist must "take appropriate steps to prevent harm to the patient and the public" and "be accountable for practising safely and maintain and demonstrate professional competence relative to [the pharmacist's] sphere of activity and scope of practice". Further, *Competence Standards for the Pharmacy Profession (2015)* require that a registered pharmacist "maintains a logical, safe and disciplined dispensing procedure" and "monitors the dispensing process for potential errors and acts promptly to mitigate them".

42. The pharmacy's SOP *Dispensing 4 — Accuracy Check (2013)* requires those checking dispensed items to check the label and dispensed medicine against the original prescription and the stock supply used to dispense the medicine, including checking the formulation, strength and quantity of medicine, and opening each dispensed bottle or packet to compare the contents with the stock supply.

43. There is no dispute that Ms C did not identify Ms B's dispensing error, when she checked the dispensing of Ms A's prescription on 15 November 2015. Ms C's normal practice is to open packets to ensure the correct medicine and strength has been selected, but on this occasion she failed to check the dispensing adequately, and thus failed to identify that the medication being dispensed did not match the label or prescription. The medications were in similar foils and have a similar appearance. As HDC has noted previously, "Checking that the patient is being dispensed the correct medication is a fundamental aspect of pharmacy practice …"[7]

44. Ms C failed to check the medication dispensed to Ms A on 15 November 2015 adequately, in accordance with the professional standards set by the Pharmacy Council of New Zealand and with the pharmacy's SOPs. I consider that Ms C failed to provide Ms A with services in accordance with professional and other relevant standards, in breach of Right 4(2) of the Code.

Opinion: The pharmacy — No Breach

45. Pharmacies have a responsibility to ensure that they have appropriate SOPs in place. Written SOPs provide set procedures to assist staff to comply with their legal and professional obligations, and are central to ensuring safe and effective dispensing. At

[7] See opinion 13HDC01618.

the time of these events, the pharmacy had relevant SOPs in place setting out a detailed process to be followed during the dispensing and checking of medications. These required dispensers to check the name, brand, strength and formulation of the medication dispensed against the prescription. The SOPs also required those checking dispensed items to check the label and dispensed medicine against the original prescription and the stock supply used to dispense the medicine, including checking the formulation, strength and quantity of medicine, and opening each dispensed bottle or packet to compare the contents with the stock supply. The SOPs were reviewed on 1 March 2014.

46. Ms B and Ms C did not follow the processes required by the SOPs, when dispensing and checking Ms A's prescription on 15 November 2015. Their usual practice is in line with the SOPs, but was not followed on this occasion. There were no other prescriptions in progress at the time, and both Ms B and Ms C were registered pharmacists. In these circumstances, I am satisfied that the dispensing error was Ms B's and Ms C's alone. The pharmacy had ensured that there were appropriate SOPs in place, as well as a sufficient number of trained staff working at the time. Therefore, I do not consider that the pharmacy breached the Code or is vicariously liable for Ms B's or Ms C's breach of the Code.

Recommendations

47. Ms B and Ms C have provided a written apology to Ms A.

48. I recommend that the pharmacy:

- Randomly audit, over a period of one month, its staff compliance with its SOPs for dispensing and checking medications, and provide HDC with the outcome of that audit within three months of the date of this report.

Follow-up actions

49. A copy of this report, with details identifying the parties removed, will be sent to the Pharmacy Council of New Zealand and the district health board, and they will be advised of Ms B's and Ms C's names.

50. A copy of this report, with details identifying the parties removed, will be sent to the New Zealand College of Pharmacists, the Health Quality and Safety Commission, and the New Zealand Pharmacovigilance Centre, and will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent clinical advice to the Commissioner

My in-house clinical advisor, general practitioner Dr David Maplesden, was asked to comment on the dispensing of tramadol capsules when "tabs" were prescribed. He provided the following advice on 30 March 2016:

> "The 50mg tramadol only comes in capsule form (sustained release — identified as tramadol SR — comes in tablet form). If the prescriber intended to supply the SR preparation the script should have been identified as such. Because the script was potentially confusing, best practice would have been for the pharmacist to check with the prescriber whether he intended 50mg capsule or 50mg SR tablet, but there was no risk of harm with the prescribing/dispensing as carried out."